CHARACTERIZATION OF EVIDENCE FOR HUMAN SYSTEM RISK ASSESSMENT

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Understanding the kinds of evidence available and using the best evidence to answer a question is critical to evidenced-based decision-making, and it requires synthesis of evidence from a variety of sources. Categorization of human system risks in spaceflight, in particular, focuses on how well the integration and interpretation of all available evidence informs the risk statement that describes the relationship between spaceflight hazards and an outcome of interest. A mature understanding and categorization of these risks requires: 1) sufficient characterization of risk, 2) sufficient knowledge to determine an acceptable level of risk (i.e., a standard), 3) development of mitigations to meet the acceptable level of risk, and 4) identification of factors affecting generalizability of the evidence to different design reference missions. In the medical research community, evidence is often ranked by increasing confidence in findings gleaned from observational and experimental research (e.g., "levels of evidence"). However, an approach based solely on aspects of experimental design is problematic in assessing human system risks for spaceflight. For spaceflight, the unique challenges and opportunities include:

1. The independent variables in most evidence are the hazards of spaceflight, such as space radiation or low gravity, which cannot be entirely duplicated in terrestrial (Earth-based) analogs.
2. Evidence is drawn from multiple sources including medical and mission operations, Lifetime Surveillance of Astronaut Health (LSAH), spaceflight research (LSDA), and relevant environmental & terrestrial databases.
3. Risk metrics based primarily on LSAH data are typically derived from available prevalence or incidence data, which may limit rigorous interpretation.
4. The timeframe for obtaining adequate spaceflight sample size (n) is very long, given the small population.
5. Randomized controlled trials are unattainable in spaceflight.
6. Collection of personal and environmental data on the astronaut population may create opportunities for advanced analytics and human-environment modeling that goes beyond that achieved in isolated experimental designs.
7. Translation of relevant research to operations is a complex, transdisciplinary enterprise in which the approach must apply across the physical, biological, behavioral, and social sciences.

The approach to synthesizing evidence must address both source and fidelity of data, and reflect the most general attributes of quality of evidence in science and engineering: reliability and validity. The authors are developing a two-factor approach which includes the various kinds of evidence required to understand risks and for the integrated interpretation of all evidence that is essential to develop standards and countermeasures. A unified framework for aggregating and assessing different kinds of evidence provides a consistent, traceable, evidence-based decision-making process to translate research to operations in an environment where engineers, scientists, physicians, and managers all engage in analyzing the trade space of vehicle design, standards, requirements and solutions for spaceflight.